REMARKS

Status of the Claims

Claims 1, 7-23, 26, 27, 52, 54-57 and 59 are pending in the present application, Claims 2, 3, 6, and 28-51 having been previously canceled, and Claims 4, 5, 24, 25, 53, and 58 having been canceled herein, and new Claim 59 having been added herein. Claims 1, 21, 22, 23, 52, 53, 54, and 57 have been amended to more clearly define the subject matter being claimed.

Brief Summary of Telephone Interview

On December 1, 2009, applicants' attorney (Michael C. King, Registration No. 44,832) conducted a telephone interview to discuss the Office Action with Examiner Utama and Primary Examiner Mosser. Before the interview, an agenda discussing aspects of the references cited and a proposed amendment were sent to Examiner Utama. During the telephone interview, each independent claim was discussed.

It was generally agreed that independent Claim 1 distinguished over the cited art.

It was generally agreed that the means plus function clauses in independent Claims 53 and 60 needed to be revised.

It was generally agreed that adding language such as follows to the remaining independent claims would enable the remaining claims to clearly distinguish over the cited art: *a simulated patent skull suture comprising a first material, a simulated fused skull suture comprising a second material, an echogenicity of the first material being substantially lower than an echogenicity of the second material.* Similarly, it could be recited that *an echogenicity of the second material being substantially higher than an echogenicity of the first material.*

Applicants' attorney would like to thank Examiner Utama and Primary Examiner Mosser for their time and willingness to discuss these issues during the Telephone Interview.

Claims Rejected Under 35 U.S.C. § 112, Second Paragraph

The Examiner has rejected Claims 21-26 and 58 as being indefinite because the Examiner believes that the filler material is not part of the claimed invention. Claim 21 has been amended to more positively recite the element to which the Examiner objects. Claim 58 has been canceled. The rejection under 35 U.S.C. § 112 should be withdrawn.

The Echogenicity of Materials Disclosed in the Prior Art

Several of the pending claims recite first and second materials whose echogenicity are substantially different, such that the first and second materials can be readily distinguished in an

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ultrasound image. These claims have been repeatedly rejected under the rationale that the materials disclosed by Gain are different, and therefore ***must have*** echogenicities that are sufficiently different such that the first and second materials can be readily distinguished in an ultrasound image.

Applicants respectfully object to the assumption that because the materials disclosed by Gain are different, those materials must be readily distinguishable in an ultrasound image. There simply is no evidence to support the assumption that the echogenicities of the materials disclosed by Gain are sufficiently different to enable those materials to be distinguished in an ultrasound image. Despite applicants' traversing this rejection, no evidentiary support of that assumption has been provided.

Gain discloses specific materials. If those materials can indeed be readily distinguished from one another in an ultrasound image, then evidence to that effect must be provided to support a *prima facie* rejection. However, none of the cited art discloses whether or not the different materials disclosed by Gain can be readily distinguished from one another in an ultrasound image.

Applicants are not disputing that *some* different materials can have sufficiently different echogenicities to enable those materials to be distinguished in ultrasound images. Applicants are simply pointing out that without ***any*** evidence about the echogenicities of the materials disclosed by Gain, it is improper to assume that those materials can be distinguished in an ultrasound image.

It has been asserted that the epoxy resin used to form Gain's cranium and the silicone elastomers used to form Gain's soft parts have different densities, and thus must have different echogenicities. No evidence has been provided as the relative densities of those materials, but even if their densities are not identical, no evidence has been presented showing that their densities result in echogenicities that are sufficiently different for the materials to be distinguishable in an ultrasound image. Again, *no evidence has been provided that the epoxy resin used to form the cranium and the silicone elastomers used to form the soft parts can be readily distinguished in an ultrasound image.*

Applicants' own disclosure provides empirical evidence of the echogenicities of three different materials, each of which presumably have different densities. Two of those materials, solid plastic and a malleable polymeric mixture, have echogenicities that are so similar that they cannot be readily distinguished in an ultrasound image, even though the materials are different. *This empirical finding absolutely contradicts the assertion that if materials are different they can be distinguished in an ultrasound image.* A third material, a starch/glue mixture, has an echogenicity that is substantially

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different than the first two materials, such that the starch/glue mixture can be readily distinguished from the plastic and malleable polymer in an ultrasound image.

Applicants' specification clearly discloses an empirical model that was imaged using ultrasound (FIGURE 5C is an ultrasound image of the model). The empirical model was made using a plastic doll's head (page 10, lines 3 and 4). Openings about 1 mm wide were made at anatomically correct locations for skull sutures (page 10, lines 4 and 5, and page 18, line 4). Openings intended to simulate a patent skull suture were filled with a starch/glue mixture (page 10, lines 5-12). Openings intended to simulate a fused skull suture were filled a malleable polymer (page 14, lines 12-25). The model was used by radiology residents and fellows, who were able to successfully distinguish the patent and fused sutures due the echogenicity difference between the different materials (page 20, lines 12-21).

Significantly, applicants empirically determined that the specified malleable polymer (page 14, lines 12-25) filling an opening in a hard plastic doll's head could not be readily distinguished from the hard plastic doll's head, while the starch/glue mixture (page 10, lines 5-12) could be readily distinguished from both the plastic doll's head and the specified malleable polymer filling an opening in the doll's head, as shown in FIGURE 5C.

Note that applicants have shown that two different materials (a plastic doll's head and a malleable polymer) can be difficult to distinguish in an ultrasound image. In contrast, the cited art provides no evidence as to whether or not the different materials disclosed by Gain can or cannot be readily distinguished in an ultrasound image, and because of that lack of evidence, a *prima facie* rejection cannot be supported.

It is also interesting to note that the materials disclosed by Gain are more like the hard plastic doll's head and the malleable polymer disclosed by applicants than a starch/glue mixture, which strongly suggests that the materials disclosed by Gain would be difficult to distinguish in an ultrasound image. Gain discloses a cranium made from epoxy resin (column 2, line 60; column 5, line 55). Such a material is similar to the plastic used for doll's heads. Gain discloses that soft parts are made using a silicone elastomer (column 11, lines 16-56). The specific malleable polymer (whose echogenicity closely matches the hard plastic doll's head) disclosed by applicants is a silicone elastomer (65%).

Applicants respectfully submit that it is illogical to on one hand can assert (without any supporting evidence) that a rigid cranium made from cured epoxy resin can be distinguished from soft parts made from a silicone elastomer in an ultrasound image, and at the same time disregard evidence from

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applicants' specification that a plastic doll's head cannot be readily distinguished from a silicone elastomer in an ultrasound image.

Claims Rejected Under 35 U.S.C. § 103(a)

Claims 1, 4-5, 7-13, 15, 18-20, 22, and 27 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,708,836 (Gain et al. - hereinafter referred to as "Gain") in view of NPL #1, "Infant Skull Model and Sculpted Head" (retrieved on June 09, 2002).

Claims 14, 16, 17, 21-26 and 52-58 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Gain in view of NPL #1, in view of U.S. Patent No. 5,609,485 (Bergman et al.) and further in view of Bergman (U.S. Patent No. 5,609,485).

Claims 4, 5, 24, 25, 53 and 58 have been canceled herein.

In the interest of reducing the complexity of the issues for the Examiner to consider in this response, the following discussion focuses on independent Claims 1, 21, 27, 52, 54, and 57. The patentability of each remaining dependent claim is not necessarily separately addressed in detail. However, applicants' decision not to discuss the differences between the cited art and each dependent claim should not be considered as an admission that applicants concur with the Examiner's conclusion that these dependent claims are not patentable over the disclosure in the cited references. Similarly, applicants' decision not to discuss differences between the prior art and every claim element, or every comment made by the Examiner, should not be considered as an admission that applicants concur with the Examiner's interpretation and assertions regarding those claims. Indeed, applicants believe that all of the dependent claims patentably distinguish over the references cited. In any event, a specific traverse of the rejection of each dependent claim is not required, since dependent claims are patentable for at least the same reasons as the independent claims from which the dependent claims ultimately depend.

Patentability of Independent Claim 1

Claim 1 has been amended to now recite *A medical simulator for training ultrasound operators to perform craniosynostosis screenings using medical ultrasound, comprising a substantially life size model of a human infant head, a skull portion of the model being primarily fabricated from a first material, said skull portion including at least one simulated patent skull suture comprising a second material,* ***the second material having an echogenicity substantially lower than an echogenicity of said first material,*** *such that each simulated patent skull suture can be readily distinguished in an ultrasound image of said model, with portions of the model corresponding to the first material appearing relatively brighter and*

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portions of the model corresponding to the second material appearing relatively darker in the ultrasound image, ***an interior volume of the model being substantially empty*** (emphasis added).

Significantly, Gain's head does not include a substantially empty interior volume. The voids initially present in the synthetic cranium are filled with simulated soft tissue, such as simulated brains and eyes. Those soft tissues are critical to Gain's model, as they are present to enable Gain's model to be used in automotive crash tests to understand how impact forces affect the various parts of the human head. Thus, modifying Gain to achieve a model having a substantially empty interior volume would render Gain ***unsatisfactory for its intended purpose*** (see MPEP 2143.01). Without the soft tissues such as the brain and eyes in the interior volume of Gain's model, accurate crash test studies could not be conducted.

The specification provides support for this amendment in the paragraph beginning at line 18 on page 18. That paragraph discusses three embodiments, a hollow head with no backing support for the fill material (functional if the fill material is sufficiently tacky), a hollow head with limited backing support for the fill material (a relatively thin layer of backing material, such as duct tape), and a hollow head filled with a hypoechoic material. Claim 1, as amended, reads on the first two of these embodiments.

Since dependent claims inherently include all of the recitation of the independent claims from which they ultimately depend, for at least the same reasons as noted above in connection with independent Claim 1, the rejection of dependent Claims 7-13, 15, and 18-20, should also be withdrawn.

Comments Applicable to Bergman

The Examiner has asserted that Bergman teaches embedding a transmitter in a mannequin, and that the transmitter can be embedded in different parts of the mannequin. The Examiner has asserted that such disclosure is equivalent to *selectively modifying a model between training sessions by enabling a filler material to be added to an opening.*

Applicants respectfully submit that the Examiner is taking elements disclosed by Bergman out of context. Bergman simply does not teach that the transmitter is moved to reconfigure the simulator. Bergman simply teaches that the specific location of the transmitter is not critical. There is no disclosure in Bergman teaching or suggesting that the location of the transmitter is ***changed*** once it has been placed in or on the mannequin. Bergman literally states: *Then a transmitter 34 can be embedded in the body at any of a plurality of desired locations, or it can be attached outside of the body at any of a plurality of locations*. That simply does not teach or suggest moving the transmitter once it has been placed to

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reconfigure the simulator, to change a simulated patent skull suture to a simulated fused skull suture, or to reconfigure the simulator in any other fashion.

Indeed, there is no need to move the transmitter, because as long as the range of the transmitter is sufficiently large, and the transmitter in/on the mannequin and the sensor in the simulated ultrasound imaging probe can communicate, the location of the transmitter is irrelevant (which is why Bergman discloses that the transmitter can be located anywhere in or on the mannequin). The function of the transmitter is to enable the relative location of the sensor in the simulated ultrasound imaging probe to be determined relative to the mannequin, such that as simulated ultrasound imaging probe is moved relative to the mannequin, simulated ultrasound unit 40 can determine the appropriate previously recorded ultrasound images to display. That requires the relative positions of the transmitter and the model to be known. If the transmitter is moved as suggested by the Examiner, then simulated ultrasound unit 40 will no longer be able to provide the correct images, until the new information about the relative positions of the transmitter and the mannequin are provided to simulated ultrasound unit 40. Moving the transmitter would require simulated ultrasound unit 40 to be reprogrammed to relate the new position of the transmitter relative to the mannequin. That requires additional effort, for no apparent benefit. A modification to a reference that provides no benefit, and instead increases complexity and cost, does not support a *prima facie* rejection.

Furthermore, the Examiner's assertion that Bergman's system is reconfigurable because the transmitter can be moved is not well reasoned. As noted above, as long as the sensor/transmitter can interact as desired, moving the transmitter provides no benefit. If there was a desire to change the ultrasound image being displayed from an image of a patent skull suture to a fused skull suture, that change could be accomplished by manipulating simulated ultrasound unit 40 (i.e., the processor that retrieves previously recorded ultrasound images), without moving the transmitter. For example, assume the simulated ultrasound imaging probe (which includes the sensor) is disposed at the anatomically correct position to acquire an ultrasound image of a skull suture. So long as the transmitter is in range of the sensor (and Bergman clearly suggests that the transmitter will be in range of the sensor regardless of where the transmitter is physically located on/in the mannequin), the position of the transmitter is irrelevant. The position of the transmitter relative to the mannequin is known, the transmitter determines the position of the sensor relative to the mannequin, and simulated ultrasound unit 40 displays an image of either a patent skull suture or a fused skull suture, depending on how simulated ultrasound unit 40 is

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programmed (i.e., depending upon the previously acquired ultrasound images that are available for display). If an ultrasound image of a fused skull suture is initially displayed, and one wishes to have an ultrasound image of a patent skull suture displayed, then all that is required is for simulated ultrasound unit 40 to access a different one of the prerecorded ultrasound images (this requires that ultrasound images of both patent and fused skull sutures were previously acquired). No change in the position of the sensor or transmitter is required. In fact, the Examiner notes that Bergman enables different pathologies to be visualized by referring to column 2, line 15. An understanding of Bergman's operating principles makes it clear that the pathology being displayed is a function of the programming of simulated ultrasound unit 40 and the location of the simulated ultrasound imaging probe including the senor, not a function of the location of the transmitter.

With respect to the Examiner's comments regarding intended use applications, the claims have been amended to positively recite structures that differ from the prior art.

Patentability of Independent Claim 21

Claim 21 has been amended to now recites:

A reconfigurable medical simulator adapted to be used to train ultrasound operators to perform craniosynostosis screenings using medical ultrasound, comprising:

(a) a substantially life size model of a human infant head, said model including a plurality of skull suture openings disposed at locations corresponding to a skull suture;

(b) a quantity of a removable first material having an echogenicity such that when the first material is disposed within an opening in the model corresponding to a skull suture, that opening will appear as a patent skull suture in an ultrasound image of the model, the first material comprising a solid or semi-solid hypoechoic material; and

(c) a quantity of a removable second material having an echogenicity such that when the second material is disposed within an opening in the model corresponding to a skull suture, that opening will appear as a fused skull suture in an ultrasound image of the model, the second material comprising a solid or semi-solid echogenic material, ***the second material having an echogenicity that is substantially higher than an echogenicity of the first material,*** *the first and second materials enabling a user to selectively reconfigure the model by controlling which of the first and second materials are used to fill specific openings, such that if an opening is filled the first material to simulate a patent skull suture and the user desires that opening to appear as a fused skull in an ultrasound image of the model, the user*

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removes the first material and fills the opening with the second material, such that the opening will appear as a fused skull suture in an ultrasound image of the model, there being a substantial difference in the echogenicities of the first and second materials, such that the first and second materials are readily distinguishable in an ultrasound image, the first and second materials being elements of the reconfigurable medical simulator.

Thus, Claim 21 recites a model head including a plurality of skull suture openings, and two different fill materials that a user can insert into the skull suture openings. The solid/semisolid fill materials are positively recited as part of the model, albeit it is up to a user to determine which openings get which fill material. The first fill material has an echogenicity that makes a skull suture opening filled with the first material appear as a patent skull suture. The second fill material has an echogenicity that makes a skull suture opening filled with the second material appear as a fused skull suture. As agreed in the above noted telephone interview, Claim 21 recites that the second material (which simulates a fused skull suture) has an echogenicity that is substantially higher than an echogenicity of the first material (which simulates a patent skull suture). This is similar to the language in Claim 1, which recites that the first material (which simulates a patent skull suture) has an echogenicity that is substantially lower than an echogenicity of the second material (which simulates a fused skull suture).

It has been previously argued that Bergman discloses a fill material (i.e., a transmitter) used to change the echogenicity of an opening in a training model. As discussed in detail above, Bergman discloses a transmitter that can be detected by a sensor that simulates an ultrasound imaging probe. The transmitter can be placed just about anywhere one desires, but moving the transmitter requires reprogramming the simulated ultrasound unit, such that the simulated ultrasound unit can determine which previously recorded images to display based on the known location of the transmitter.

Bergman's system is reconfigurable, because different prerecorded ultrasound images can be used, not because the transmitter location affects the image displayed. Actually, moving the transmitter from its initial position would change the images being displayed, if the ultrasound imaging machine were not reprogrammed to track the transmitter's position, as the movement of the transmitter would change how the system tracks the relative position of the simulated ultrasound imaging probe. In other words, if you move the transmitter and reprogram the simulated ultrasound imaging machine, there is no change in the images displayed. If you move the transmitter and don't reprogram the simulated ultrasound imaging machine, there is a change in the images displayed, because the system is no longer correctly tracking the

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relative position of the simulated ultrasound imagining probe (i.e., the probe might be positioned to acquire an image of the abdomen, but the system displays an ultrasound image of the leg).

Bergman simply does not teach or suggest that moving the location of the transmitter changes the image to be displayed. Bergman most definitely does not teach or suggest that putting the transmitter in an opening simulating a skull suture would change the previously recorded ultrasound image being displayed from a patent skull suture to a fused skull suture.

With respect to the recited fill materials, the recited first fill material ***must*** (when inserted into a skull suture opening and an ultrasound image of that opening is acquired) have an echogenicity that causes the opening to appear in the ultrasound image as a patent skull suture. The recited second fill material ***must*** (when inserted into a skull suture opening and an ultrasound image of that opening is acquired) have an echogenicity that causes the opening to appear in the ultrasound image as a fused skull suture. Even if Bergman's transmitter was small enough to be inserted in an opening in Gain's model simulating a skull sutures, you might be able to see the transmitter itself in the ultrasound images. But applicants do not understand how it can be argued that the transmitter would look like either a fused or a patent skull suture. The claim requires that the first and second material actually look like real patent or fused skull sutures in an ultrasound image. No evidence has been submitted as to the echogenicity of Bergman's transmitters, thus there is no basis for asserting that a transmitter would appear as either a patent or fused skull suture in an ultrasound image. Finally, Bergman's transmitters cannot logically be equivalent to ***both*** the first and second materials, and none of the other cited art discloses materials that are moveable from one opening to the next. The cited art simply does not teach or suggest a model with a plurality of skull suture openings, and two different fill materials of substantially different echogenicities, that can be used to selectively fill the skull suture openings.

Since dependent claims inherently include all of the recitation of the independent claims from which they ultimately depend, for at least the same reasons as noted above in connection with independent Claim 21, the rejection of dependent Claims 22, 23, and 26 should also be withdrawn.

Patentability of Independent Claim 27

As currently amended, Claim 27 recites that the patent and fused skull sutures are replaceable and interchangeable, *such that a user can change the relative locations of each replaceable simulated patent skull suture and each replaceable simulated fused skull suture to reconfigure the ultrasound trainer.*

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As agreed in the above noted telephone interview, Claim 27 also recites that the first material (which simulates each patent skull suture) has an echogenicity that is substantially lower than an echogenicity of the second material (which simulates each fused skull suture).

Further, it must be recognized that the simulator of Claim 27 is configured to simulate a fused skull suture in a non obvious manner, which is not taught or suggest in the cited art.

Anatomically speaking, a fused skull suture represents a joint between adjacent boney skull plates, with little or no gap at the joint. A patent skull suture represents a joint between adjacent boney skull plates, with a definite gap between the plates, the gap being filled with tissue. Gain includes a realistic adult cranium, including fused skull sutures implemented by a mass of epoxy resin without an opening or gap. The cranium proximate the patent skull sutures is cast as a single mass (it appears as if the jaw is a separate casting). The simulator of Claim 27 simulates a fused skull suture by 1) having an opening at the fused skull suture, and 2) filling that opening with a filler material that will simulate a fused skull suture. The cited art simply does not teach or suggest a fused skull suture comprising an opening filled with a echogenic material. Based on the disclosure of Gain and NPL#1, only patent skull sutures would be formed using an opening and a fill material.

Thus, it should be apparent that Claim 27 is novel and non-obvious in view of the art cited. For this reason, the rejection of independent Claim 27 under 35 U.S.C. § 103(a) should be withdrawn because the cited art does not teach or suggest all of the recitation of Claim 27.

Patentability of Independent Claim 52

Claim 52 as amended recites:

A reconfigurable medical simulator for training ultrasound operators to perform craniosynostosis screenings using medical ultrasound, comprising a substantially life-size model of a human infant head, said model including two eyes, a mouth, two ears, and a plurality of openings, each opening simulating a skull suture, at least one of the plurality of openings being filled with a removable first material to simulate a patent skull suture, and at least one of the plurality of openings being filled with a removable second material to simulate a fused skull suture, ***an echogenicity of the removable first material being substantially lower than an echogenicity of the removable second material****, a difference in echogenicity of the removable first material in each simulated patent skull suture and the removable second material in each simulated fused skull suture enabling each simulated patent skull suture to be readily distinguishable from non suture portions of the model and from each simulated fused suture in an*

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ultrasound image of said model, the removable first material and the removable second material being interchangeable, such that a user can change the relative locations of each simulated patent skull suture and each simulated fused skull suture to reconfigure the ultrasound trainer (emphasis added).

As agreed in the above noted telephone interview, Claim 52 recites that the first material (which simulates each patent skull suture) has an echogenicity that is substantially lower than an echogenicity of the second material (which simulates each fused skull suture).

Claim 52 patentably distinguishes over the cited art for substantially the same reasons as Claim 21 and 27. Note Claim 52 positively recites the first and second materials, thus there appears no basis for an indefiniteness rejection of this claim.

Patentability of Independent Claims 54 and 57

Claims 54 and 57 are rejected over a combination of Gain, the first NPL reference, Cecchi, and Bergman.

As agreed in the above noted telephone interview, Claims 54 and 57 recite that the second material (which simulates each patent skull suture) has an echogenicity that is substantially lower than an echogenicity of the first material (which forms the skull), and that the third material (which simulates each fused skull suture) has an echogenicity that is substantially higher than an echogenicity of the second material (which simulates each patent skull suture).

As discussed above, Bergman 8:35-50 ***does not*** disclose the concepts of a third material filling an opening as asserted in this rejection.

Furthermore, as noted above, Gain discloses that a simulated fused skull suture is fabricated by casting a cranium without an opening at the area corresponding the fused skull suture. The simulator of Claims 54 and 57 simulate a fused skull suture by 1) having an opening at the fused skull suture, and 2) filling that opening with a filler material that will simulate a fused skull suture. The cited art simply does not teach or suggest a fused skull suture comprising an opening filled with a echogenic material. Based on the disclosure of Gain and NPL#1, only patent skull sutures would be formed using an opening and a fill material.

Accordingly, the rejection of independent Claims 54 and 57 under 35 U.S.C. § 103(a) should be withdrawn because the cited art does not teach or suggest all of the recitation of Claims 54 and 57.

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Since dependent claims inherently include all of the recitation of the independent claims from which they ultimately depend, for at least the same reasons as noted above in connection with independent Claim 54, the rejection of dependent Claims 55 and 56 should also be withdrawn.

Patentability of Independent Claim 59

Claim 59 is similar to Claim 21, but recites that the first fill material comprises starch and glue mixture, and the second fill material comprises a silicone elastomer.

Claim 59 specifically recites that the second material (the silicone elastomer to simulate the fused skull suture) is substantially more echogenic than the first material (the starch/glue mixture to simulate the patent skull suture).

The starch and glue fill material distinguishes over the cited art. There simply has been no evidence presented of fabricating any structure at all out of a starch/glue mixture to control the appearance of a structure in an ultrasound image.

Conclusion

Upon consideration of the amendment to the claims and the Remarks set forth above, applicants respectfully request that the Examiner telephone them to discuss additional amendments, if the amendments have not addressed the Examiner's concerns with respect to 35 U.S.C. § 112.

Respectfully submitted,

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